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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/774,936 | 01/31/2001 | Bradley A. Ozenberger | AHP 98126 1C1 | 5327 |

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| EXAMINER | |
|---|---|
| GUCKER, STEPHEN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/774,936 | OZENBERGER ET AL. | |
| | Examiner | Art Unit | |
| | Stephen Gucker | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 January 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *13-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/29/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

**1.** Applicant's election with traverse of Group I, claims 1-12 and 16-18, filed 12/2/03 is acknowledged. The traversal is on the ground(s) that claim 11 serves as the linking claim for claims 13-15 and that if claim 11 is found to be allowable, claims 13-15 shall be entitled to examination. This is not found persuasive because claims 13-15 are improper dependent claims. Claim 13, which is dependent on claim 11 and from which claims 14-15 depend from, encompasses very short probe or primer sequences (i.e. two nucleotides) which may not encode an amino acid at all, let alone a peptide comprising the amino acid sequence of SEQ ID NO:2 from amino acid 1 to amino acid 67, as is required by claim 11. Since the dependent claim broadens the scope of the claim from which it depends, it is not a proper dependent claim and cannot serve as a proper linking claim.

The requirement is still deemed proper and is therefore made FINAL.

**2.** It is noted that this application appears to claim subject matter disclosed in prior Applications No. 09/172,990, filed 10/14/98, and 09/060,609, filed 4/15/98 (in addition to the provisional application 60/064,583, filed 4/16/97). A reference to the prior applications appears in the first sentence of the specification. However, for benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay

was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

**3.** This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for these reason(s): Many oligonucleotide sequences appear throughout the specification that require SEQ ID NOs; either these sequences require their own unique SEQ ID NOs or identification of where these oligonucleotide sequences occur in the SEQ ID NOs already of record (e.g. SEQ ID NO:1, nucleotides 1-2, etc.). Some of these sequences are found, for example, on page 24, lines 19-20, page 25, lines 6-7, page 26, lines 3-4 and lines 27-28, etc.

**4. Applicant should review the instant Application in its entirety for compliance with the sequence rules, paying particular attention that all sequences recited throughout the disclosure in its entirety have SEQ ID NOs and that the SEQ ID NOs recited are found in both the CRF and paper copy of the Sequence Listing. Applicant must comply with the sequence rules and the remainder of the entire Office action simultaneously. Otherwise, the applicant will receive a Notice of Non-Responsive Reply.**

**5.** Applicant is given the shortened statutory period of THREE MONTHS from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a

petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period.

**6.** 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-12 and 16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims as written encompass products of nature which do not show the hand of man. The grounds of this rejection could be obviated by amending the claims to recite an isolated or purified polynucleotide or nucleic acid.

**7.** The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**8.** Claims 2, 10, and 16-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide, nucleic acid, or host cell comprising SEQ ID NO:1 or nucleic acids capable of hybridizing under specified and recited conditions to the complement of SEQ ID NO:1 that encode a β-amyloid peptide-binding protein (BBP), does not reasonably provide enablement for every polynucleotide that encodes a β-amyloid peptide-binding protein (BBP) or every nucleic acid capable of hybridizing to SEQ ID NO:1 or its complement. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claim 2 and

claim 10 (b) can be interpreted as claiming any polynucleotide comprising or consisting of the nucleotide sequence of any β-amyloid peptide-binding protein (BBP). The broad scope of these claims is not commensurate with the disclosure because while only a single species of polynucleotide encoding a β-amyloid peptide-binding protein (BBP) is disclosed, the claims encompass any and every polynucleotide that encodes a protein with this particular biological function. Because of the high degree of unpredictability in the peptide arts regarding amino acid deletions, additions, and substitutions, and the effect these alterations have on biological activity (see Rudinger, particularly page 6), the instant disclosure is not enabling for placing this broad genus into the hands of the public. The single species disclosed is not adequately representative of every polynucleotide that possesses the desired activity. For example, the disclosure is drawn to an encoded receptor protein for β-amyloid. However, by using β-amyloid as an immunogen, many different antibodies could be generated that would meet the claim limitation of being a β-amyloid peptide-binding protein (BBP) (because antibodies are proteins that bind antigens), but such β-amyloid peptide-binding antibodies would have no chemical or structural features in common with the disclosed invention and, as such, are not envisioned by the instant disclosure.

Claim 10 is also not enabled for the additional reason that it encompasses any nucleic acid capable of hybridizing under stringent conditions to a polynucleotide or complement of SEQ ID NO:1. First, "stringent conditions" is indefinite because it encompasses conditions that are non-selective that allow an infinite amount of hybridization to occur (collectively known as low stringency conditions), to conditions

that are highly selective for polynucleotides closely similar in structure to SEQ ID NO:1 (collectively known as high stringency conditions). Second, while the skilled artisan may be able to make an infinite number of polynucleotides that hybridize to SEQ ID NO:1 or its complement under low stringency conditions, the fact of the matter is that very low stringency conditions would let any and every known and unknown polynucleotide (from a simple two-nucleotide sequence to thousands of nucleotides) hybridize to SEQ ID NO:1 or its complement, and the skilled artisan would not be able to use such sequences in an enabling manner because the vast majority of such sequences would not be selective for detecting or making SEQ ID NO:1 or its complement as a probe or primer because of the very low stringency conditions encompassed by the claim would encompass hybridizing sequences that have little structural features in common with SEQ ID NO:1 or its complement. Third, the vast majority of these encompassed sequences that are capable of hybridizing under very low stringency conditions would also not encode any polypeptide that could be used in any meaningful way at all, let alone encode a polypeptide that had a β-amyloid peptide-binding capability. Finally, it is noted by the Examiner that polynucleotides that are more properly defined as probe, primer, or antisense sequences are not part of the elected invention, Group I, but more properly belong to the non-elected invention, Group II, and it is suggested by the Examiner that a clear demarcation be established and maintained between the two Groups to avoid potential double-patenting rejections in any future application drawn to the invention of Group II filed as a continuing application that names the instant Application as a parent.

The grounds of this rejection could be partially obviated by amending claim 2 and claim 10 (b) to recite "a β-amyloid peptide-binding protein (BBP) designated as clone BBP1-fl...". In which case, claim 3 and claim 10 (c) should be canceled as being duplicative of the amended claims. Additionally, it is suggested that claim 10 be amended to recite "A nucleic acid encoding a β-amyloid peptide-binding protein (BBP) capable of hybridizing..." and then go on to recite specific high stringency conditions (ionic concentration, temperature, number of washings, etc.) taken from the specification in order to further obviate the grounds of this rejection.

**9.** Claims 2, 10, and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For much the same reasons given in **¶8** set forth above, the specification fails to adequately describe the very broad genus of β-amyloid peptide-binding proteins (BBP) that are not encoded by SEQ ID NO:1 or that do not hybridize to SEQ ID NO:1 under specified and recited high stringency conditions. The grounds of this rejection could be obviated by amending the claims as suggested in **¶8** set forth above.

**10.** Claims 2-3, 6-7, 10, and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use

the invention. The specification does not provide a repeatable method for obtaining clone BBP-fl deposited under accession number ATCC 98617 or clone pEK 196 deposited under accession number ATCC 98399, and it is not guaranteed to be a readily available material. Since other clones made would not be expected to have the exact same identifying characteristics (i.e. identical sequences) as the deposited clones, it would take undue experimentation to repeatedly try to make and then to determine whether other clones would contain the same identifying characteristics as the deposited clones. Since deposits has been made under the provisions of the Budapest Treaty (see instant specification, page 26, lines 8-13), the filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, and that all restrictions upon *public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository* is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Applicant's attention is directed to *In re Lundack*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

**11.** The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2,10 and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 and 10 (b) recite "...β-amyloid peptide-binding protein (BBP) *and of* clone..." (italics added). It would appear from the claim language that Applicant intends to claim a sequence comprising the deposited clone AND another completely different sequence encoding a β-amyloid peptide-binding protein (BBP). Alternatively, Applicant could be trying to claim two separate sequences, one the deposited clone and the other, an unknown sequence encoding a β-amyloid peptide-binding protein (BBP). The claims are therefore vague and indefinite. It is the Examiner's opinion after speaking with Applicant's representative that what Applicant's intent is to claim the sequence of the deposited clone itself. In which case, the grounds of this rejection could be partially obviated by amending the claims to recite "a β-amyloid peptide-binding protein (BBP) *designated as* clone...".

The metes and bounds of claims 10 and 16-18 are further indefinite because "hybridizing under stringent conditions" does not set forth and recite in the claims the specific conditions under which the hybridizing is taking place. Dependent upon the specific conditions taken from the specification, the metes and bounds of the claim will change with the temperature used, the concentration of reagents, the number of washings performed, etc., as the claims belong to the category known as "a product by process." Specifying and reciting the hybridization conditions intended (i.e. the process by which the product is defined) will further obviate the grounds of this rejection.

**12.** No claim is allowed.

**13.** Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone number for this Group is currently (703) 872-9306.

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Stephen Gucker

March 22, 2004